

## **REMARKS**

Claims 13-26 and 28 stand rejected. Claims 13 and 15 are presently cancelled. New Claims 29 and 30 have been added. Claims 14, 16-26, and 28-30 are currently pending. Claim 25 has been amended to correct for a typographical mistake. The amendment changes “fo” to “of.” Support for the amendment can be found within the previous version of Claim 25, for example. Claim 14 has been amended to incorporate the explicit limitations set forth in Claim 13. Support for this amendment can be found in the previous claims and the specification, in particular, Claims 13 and 14. Claim 16 has been amended to adjust its dependency. Support for the amendment can be found throughout the specification and in the previous Claims 13-16. Claim 24 has been amended to literally incorporate the limitations of now cancelled Claim 13 into Claim 24. Support for the amendment can be found in the specification and the claims, for example, Claims 13 and 24. Claims 29 and 30 have been added. Support for the new claims can be found throughout the specification and claims, for example, figure 2, figure 3, figure 5, p. 17, lines 4-10 and p. 21, lines 6-15. No new matter has been added by these amendments.

Reconsideration of the pending rejections in view of the following remarks is respectfully requested.

### **Submission of Missing References**

The previous Office Action listed several references that were previously provided with an Information Disclosure Statement but were not available to the Examiner at the time of the examination. The applicants submit herewith additional copies of the requested references.

### **Rejection under 35 U.S.C. §112**

Claims 24-26 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to “reasonably provide enablement for the methods of treatment of type I diabetes or bulimia.” The Office Action states that this is a scope of enablement rejection. As an initial matter, the applicants note that Claim 26 is a composition claim and does not recite a method of treatment of bulimia or type I diabetes. The applicants assume that the rejection of Claims 24-26 was in error and that the rejection was instead intended to be for Claims 24 and 25 only.

Concerning Claims 24 and 25, the Examiner found that the prior art teaches that type I diabetes is not associated with obesity, and that “to date, the art has not established a connection

[between] abnormal expression of the OB gene and type I diabetes, or bulimia.” (Office Action, page 4). More particularly, the Examiner found that the current application does not teach “that type I diabetes or bulimia is related to obesity, or to an association with the abnormal expression or function of the OB gene. The nexus between type I diabetes or bulimia and obesity or abnormal expression or function of the OB gene is nowhere established.” The Examiner concludes that in light of this, one of skill in the art would have no expectation of success. The applicants respectfully traverse.

The applicants disagree and respectfully direct the Examiner’s attention to lines 11-15 on page 17 of the specification. This section explicitly identifies both type I diabetes and bulimia as metabolic disorders that can be treated via OB derivatives. Thus, the specification teaches one of skill in the art that there is a nexus between type I diabetes and bulimia and the OB protein.

The applicants respectfully submit that because the nexus between the disorders and the OB protein is explicitly established in the specification, the finding that the prior art teaches that there is no nexus between these disorders and obesity is irrelevant. Additionally, that assertion that the quantity of experimentation would be undue because no nexus has been established between OB genes and the disorders is incorrect because a nexus has been established in the specification.

Other factors also support the fact that the claims are enabled. For example, those of skill in molecular biology arts in the 1995 time period were generally highly skilled practitioners with an advanced degree or a high level of training. Additionally, the claims are directed to a finite number of identifiable disorders and thus are not excessively broad. Moreover, the claims are directed to a method that employs the compound of presently cancelled Claim 13, which was and still is fully enabled, suggesting that a method of using the composition as described in the specification should also be fully enabled. Finally, as discussed above, the specification itself explicitly establishes the nexus that the Examiner is requesting.

The only asserted deficiency in the present specification is that a nexus between OB proteins and the two disorders is not taught. As the specification does explicitly establish such a nexus, and as one of skill in the art would understand this nexus in light of the teaching of the present application, the applicants submit that the full scope of present Claims 24 and 25 are enabled.

Finally, the applicants note that the Office Action has not addressed why Claim 24 would not be enabled. The rejection in the Office Action is directed specifically and exclusively to those limitations recited in Claim 25. Indeed, the Office Action appears to acknowledge that the technique is generally enabled (page 3, first paragraph, and page 4, first whole paragraph, Office Action Mailed 09/13/04).

In light of the above, the applicants request that the rejection be withdrawn and Claims 24-26 allowed.

**Rejection under 35 U.S.C. §102(e)**

Claims 13 and 15 stand rejected under 35 U.S.C. §102(e) as being anticipated by Pellymounter, U.S. Patent Application Publication No. 2003/0203837, filed 5/30/2003 and claiming priority to 11/22/1995.

In an effort to expedite the prosecution of the application, the applicants have presently cancelled Claims 13 and 15. The applicants reserve the right to pursue the subject matter of cancelled Claims 13 and 15 at a later point in time. As Claims 13 and 15 have been cancelled, the applicants request that the rejection be withdrawn.

**Rejections under 35 U.S.C. §103(a)**

Claims 13-26 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over any one of Zhang et al. (hereinafter “Zhang”), Basinski et al. (‘744 or ‘886, (hereinafter “Basinski”)), DiMarchi et al (‘954 or ‘336, hereinafter “DiMarchi”), in view of Shin et al. (hereinafter “Shin”) or Ashkenazi et al. (hereinafter “Ashkenazi”).

The applicants note this rejection has already been overcome and withdrawn during the current prosecution of this application. This rejection was raised in the first Office Action (mailed 5/27/98). Importantly, this rejection was withdrawn as the previous Examiner deemed the amendments and arguments presented in the response to the Office Action “sufficient to obviate all of the previous rejections, thus, claims 13-26 and 28 are free of all prior rejections and the prior art.” (Examiner Communication, mailed 3/12/99, page 2). In this regard, Applicants note that the Patent and Trademark Office has a duty to apply consistent standards in examining patent applications. *C.f. In re Cortwright*, 165 F.3d 1353, 49 U.S.P.Q.2d 1464, 1467 (Fed. Cir. 1999).

It appears that the Examiner Communication, sent approximately five years ago by a previous Examiner, may have been overlooked by the present Examiner in the creation of the pending Office Action, as there was no statement in the Office Action that the decision was being reversed. This is supported by the fact that the current Office Action asserts that the rejection "is maintained," when in fact the rejection was previously withdrawn.

The applicants note that "[f]ull faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 139, 57 USPQ2d 1449, 1499-50 (D. Mass. 2001)." (M.P.E.P. §706.04, May 2004 Revision). As such, the applicants submit that the previous arguments were sufficient for the reasons pointed out by the applicants in their previous reply (mailed 11/25/98) and for the reasons stated by the Examiner in the previous Communication (3/12/99).

The applicants would also note that the references cited by the Examiner are not as relevant as the references cited by the applicants in their previous Response. In particular, the references Maffei et al, Coleman and Campfield et al. directly discuss the OB proteins and OB genes. On the other hand, the references in the previous Office Action (*e.g.*, Shin et al. and Ashkenazi et al.) do not appear to be directed to OB proteins. The entirety of the prior art must be considered (A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) M.P.E.P. §2141.02). The applicants submit that one of skill in the art would not have ignored the teachings of Coleman, Campfield et al., and Maffei et al., which are directed to relevant proteins (*e.g.*, OB proteins), and instead followed teachings in references that address unrelated proteins. Additionally, no reason has been supplied as to why one of skill in the art would ignore teachings directly relevant to the protein and questions at hand, and instead look to teachings in unrelated proteins or systems.

Additionally, it is asserted in the Office Action that the fact that “earlier OB protein studies may not have fully recognized the nature of the interaction of the protein with its cognate receptor, and where such receptors were located, does not detract from the obviousness.” (Page 7). To the contrary, what one of skill in the art, at the time of the invention, would have believed or not believed concerning the above facts directly impacts what one of skill in the art would have been motivated to do and would have expected as an outcome. The fact that those of skill in the art believed that these proteins were expressed in the brain suggests that anything that targets the protein would need to be able to pass the blood brain barrier. That OB protein did not appear to access the brain when expressed in adipose tissue would further suggest to one of skill in the art that an OB protein would not function in this system. Moreover, there is nothing to suggest that the chimeric versions of such a protein would function at all or function in a superior manner. The courts are clear that a novel insight can be sufficient to establish nonobviousness (“[b]ecause that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art.” 713 F.2d at 785, 218 U.S.P.Q. at 700 (citations omitted)) (M.P.E.P. §2141.02).

Thus, it is clear that one of skill in the art would not have been motivated to make the claimed combination and would not have had any expectation that the claimed combination would have worked for its intended purpose. In light of this, a *prima facie* case of obviousness has not been established.

In light of the above, the applicants request that the rejection be withdrawn and Claims 14, 16-26 and 28 allowed.

#### **New Claims 29 and 30**

New Claims 29 and 30 depend from Claim 24. As noted above, there is adequate enabling support for Claim 24, and there is additional enabling support for Claims 29 and 30 in the specification. For example, support can be found in figure 2, figure 3, figure 5, p. 17, lines 4-10 and p. 21, lines 6-15. Additionally, as noted above, Claim 24 is nonobvious in light of the cited references. As Claims 29 and 30 depend from Claim 24, Claims 29 and 30 are also nonobvious.

**Conclusion**

Applicants respectfully submit that for the above recited reasons the current rejections should be withdrawn and that the present application is in condition for allowance. If, however, some issue remains, the Examiner is cordially invited to telephone the undersigned in order to resolve such issue promptly. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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